PRIA Fee Category Table – External Review and Miscellaneous Actions

Table 19.

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
[HYPERLINK "http://www2.epa.gov/pria-fees/m001-pria-fee-category"]	202	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote4"]	9	7,938
[HYPERLINK "http://www2.epa.gov/pria-fees/m002-pria-fee-category"]	203	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote4"]	9	7,938
[HYPERLINK "http://www2.epa.gov/pria-fees/m003-pria-fee-category"]	204	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific	12	63,945

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote5"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/m004-pria-fee-category"]	205	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active	18	63,945

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote5"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/m005-pria-fee-category"]	206	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote6"] [	9	22,050

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote7"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/m006-pria-fee-category"]	207	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products)[8]	1	277
[HYPERLINK "http://www2.epa.gov/pria-fees/m007-pria-fee-category"]	208	Request to extend Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(ii)	12	5,513
[HYPERLINK "http://www2.epa.gov/pria-fees/m008-pria-fee-category"]	209	Request to grant Exclusive Use of data as provided by FIFRA Section 3(c)(1)(F)(vi) for a minor use, when a FIFRA Section 2(ll)(2) determination is required	15	1,654
M009	210 (new)	Non-FIFRA Regulated Determination: Applicant initiated, per product	4	2,363
M010	211 (new)	Conditional ruling on pre-application, product substantial similarity	4	2,363
M011	212 (new)	Label amendment to add the DfE logo; requires data review;	4	3,648

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-external-review-and-miscellaneous-actions" \l "footnote1"][1]	FY'17 & FY'18 Registration Service Fee ($)
		no other label changes [9]		

[1]A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

[2]If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time line for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

[3]If EPA data rules are amended to newly require clearance under section 408 of the FFDCA for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

[4]Any other covered application that is associated with and dependent on the HSRB review will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.

[5]Any other covered application that is associated with and dependent on the SAP review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.

[6]An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

[7]Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of

the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

[8]Due to low fee and short time frame this category is not eligible for small business waivers. Gold seal applies to one registered product.

[9]This category includes amendments the sole purpose of which is to add DfE (or equivalent terms that do not use "safe" or derivatives of "safe") logos to a label. DfE is a voluntary program. A label bearing a DfE logo is not considered an Agency endorsement because the ingredients in the qualifying product must meet objective, scientific criteria established and widely publicized by EPA (https://www.epa.gov/saferchoice).